

K061302

JUN 23 2006

510(k) Summary

as required by 807.92

1. Company Identification

MITSUBISHI ELECTRIC CORPORATION
KYOTO WORKS
1 Zusho Baba, Nagaokakyo city,
Kyoto 617-8550

2. Contact Person

Aki Nakamura (Mr.), Manager
VCP Engineering Group 1
Professional Electronics Department
Tel: 011-81-75-958-3510 Fax: 011-81-75-958-3708

3. Date of Submission

May 2, 2006

4. Establishment Registration No.

Not assigned yet

5. Device Trade name

Digital Printer P6000D series Model P6000DU

6. Common Name

Medical Image Hardcopy Device

7. Classification

Medical image hardcopy device was reviewed by the Radiology Panel and classified in Class II per 21 CFR 892. 2040.

8. Product Code

LMC

9. Description of Device

Digital Printer P6000D series Model P6000DU receives signals from diagnostic imaging equipment or a personal computer, and automatically prints and ejects the received image data on 8x10" sized film/thermal paper. It does not incorporate laser scanning unit. The control unit processes and controls image data and performs control of the whole device. This device is not intended for mammography use.

10. Intended Use

Digital Printer P6000D series Model P6000DU receives signals from diagnostic imaging equipment or a personal computer, and automatically prints and ejects the received image data on the film/thermal paper. This device is not intended for mammography use.

11. Compliance Standard

Digital Printer P6000D series Model P6000DU complies with the following standards:

UL60601-1 - Medical Electrical Equipment, Part 1: General Requirements for Safety

IEC60601-1-2 - Medical electrical equipment - Part 1-2: General requirements for safety -

Collateral standard: Electromagnetic compatibility - Requirements and tests

12. Predicate Device

Drystar 5300M manufactured by Agfa Corporation, 510(k) No.: K032635.

13. Technological Characteristics

Digital Printer P6000D series Model P6000DU has same technological characteristics as Drystar 5300M. Model P6000DU uses a thermal process to produce medical images.

14. Conclusion

Based on above-mentioned items, it is concluded that Digital Printer P6000D series Model P6000DU is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

AUG - 3 2006

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Shinichi Yamanaka, Safety Department
Mitsubishi Electric Corporation
Satoru Kato, Senior Manager
Professional Electric Department, Kyoto Works
1 Zusho Baba, Nagaokakyo City
Kyoto 617-8550 JAPAN

Re: K061302

Trade/Device Name: Digital Printer P6000D series Model P6000DU
Regulation Number: 21 CFR 892.2040
Regulation Name: Medical image hardcopy device
Regulatory Class: II
Product Code: LMC
Dated: May 8, 2006
Received: May 10, 2006

Dear Mr. Yamanaka:

This letter corrects our substantially equivalent letter of June 23, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must



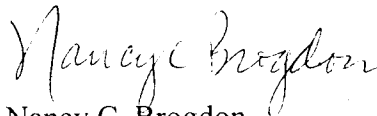
Protecting and Promoting Public Health

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in cursive script that reads "Nancy C. Brogdon".

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known) :

Device Name : Digital Printer P6000D series Model P6000DU

Indications For Use:

Digital Printer P6000D series Model P6000DU receives signals from diagnostic imaging equipment or a personal computer, and automatically prints and ejects the received image data on the film/thermal paper. This device is not intended for mammography use.

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and
Radiological Devices
510(k) Number K061302

Page 1 of _____